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In the Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA, PETITIONER

v.

THOMAS W. MOORE, JR.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE UNITED STATES

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BRIEF FOR THE UNITED STATES

OPINION BELOW

The opinion of the court of appeals (Pet. App. A) is reported at 505 F. 2d 426.

JURISDICTION

The judgment of the court of appeals (Pet. App. B) was entered on October 18, 1974. On November 14, 1974, the Chief Justice extended the time for filing a petition for a writ of certiorari to and including December 17, 1974. The petition was filed on the latter date and was granted on February 18, 1975 (App. 142). The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether a licensed physician, registered under the Controlled Substances Act to prescribe and dispense certain controlled substances for legitimate medical purposes, is immune from prosecution under the felony provision of the Act prohibiting the unlawful distribution or dispensation of a controlled substance.

STATUTES AND REGULATION INVOLVED

Because of their length, the pertinent provisions of the Controlled Substances Act (Pub. L. 91–513, 84 Stat. 1242, 21 U.S.C. 801, et seq.),[1] relevant sections of other statutes and the pertinent regulation, 21 C.F.R. 306.04 (1973 ed.),[2] are set forth in the appendix to this brief.

STATEMENT

1. Respondent is a physician who, at the time of the events in question, was licensed to practice medicine in the District of Columbia and registered under the Controlled Substances Act to prescribe methadone.[3] He

[1] Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91–513, 84 Stat. 1242, is designated the Controlled Substances Act (21 U.S.C. 801 through 904). Throughout this brief, references to sections of the Controlled Substances Act will be to section numbers of the Act as codified, *e.g.*, 21 U.S.C. 841(a).

[2] This regulation was redesignated 21 C.F.R. 1306.04 in the 1974 revision of Title 21 of the Code of Federal Regulations.

[3] A "license" is issued by the state (or here, the District of Columbia, through its Commission on Licensure to Practice the Healing Art) to enable a medical practitioner to engage in his profession. Generally two "registrations" are issued to enable a licensed practitioner to handle drugs or—to use the term employed by the statute—controlled substances. One registration is issued by the Attorney General, who has delegated his authority to the Drug Enforcement Agency (DEA) or, at the time of the events at issue here, its predecessor, the Bureau of Narcotics and Dangerous Drugs (BNDD); and the other registration is issued by the state or other licensing authority. See Baumgartner and Morrell, *Pharmaceutical Industry Regulation by the Department of Justice*, 23 Syr. L. Rev. 785, 810–813 and n. 65 (1972). In the case of a "practitioner"—defined in 21 U.S.C. 802(20), as, *inter alia*, "a physician, dentist, veterinarian, scientific investigator, pharmacy [or] hospital * * *"—registration by the DEA is mandatory in most instances (and was mandatory in all cases, at the time respondent received his registration) if the practitioner is authorized to dispense drugs or conduct research under the law of the state in which he practices. 21 U.S.C. 823(f). See Baumgartner and Morrell, *supra*, 23 Syr. L. Rev. at 810–811.

was charged in a 639-count indictment filed on June 27, 1972, in the United States District Court for the District of Columbia, with the unlawful distribution and dispensation of methadone (dolophine), a Schedule II controlled substance, in violation of 21 U.S.C. 841(a)(1).[4] The indictment alleged that over a five and one-half month period, from September 27, 1971 to February 9, 1972, respondent had illegally distributed and dispensed methadone on repeated occasions to twenty-five different persons (App. 3–29).

At the court's request, the government orally gave a more explicit statement of the theory of its case. In brief, that theory was that respondent had issued methadone prescriptions other than for purposes of detoxification in the course of a legitimate profes-

[4] A Schedule II controlled substance is a "drug or other substance [which] has a high potential for abuse * * * [, which] has a currently accepted medical use in treatment * * *," and the abuse of which "may lead to severe psychological or physical dependence." 21 U.S.C. 812(b)(2). See 21 U.S.C. 812(c)(Schedule II)(b)(11).

sional practice[5] and thereby violated 21 U.S.C. 841 (a)(1).[6]

[5] As established by expert testimony at respondent's trial, methadone is an addictive drug used in the treatment of heroin addicts. It reduces or eliminates the addict's craving for heroin while, if properly administered, it does not produce the euphoric "high" of heroin. There are two primary methods in which methadone is used in the treatment of addicts: "detoxification" and "maintenance." Detoxification involves giving the addict a large dose of methadone for the first few days of treatment in order to keep him free from withdrawal symptoms, after which the dose is gradually reduced, ultimately to achieve abstinence from all drugs. Maintenance involves giving the addict a fixed dose of methadone once a day for an indefinite period in order to keep him from taking heroin. (Tr. 337–424, 435–474, 551–574). At the time of respondent's conduct, there were no statutory definitions of detoxification and maintenance; but the Narcotic Addict Treatment Act of 1974, Pub. L. 93–281, 88 Stat. 124, subsequently has provided definitions. See 21 U.S.C. 802(27) and (28).

[6] The government's theory, received by the court as "in the nature of a Bill of Particulars" (App. 37), was in two parts. First, the Controlled Substances Act permits a doctor registered under the Act to dispense drugs covered by his registration, if the drugs are dispensed in the course of his professional practice (App. 35). 21 C.F.R. 306.04(a) (1973 ed.) restates this limitation of a doctor's authority to dispense through prescriptions, which must "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his medical practice." The government contended that "the conduct by Dr. Moore in giving out these prescriptions was not for a legitimate medical purpose, and * * * that he was not acting in the usual course of his professional practice" (App. 36).

Second, 21 C.F.R. 306.04(c) (1973 ed.) prohibits prescribing narcotic controlled substances "to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs * * *." While 21 C.F.R. 306.07 (1973 ed.) allows the "administering or dispensing directly" of such drugs for drug maintenance, it does not permit—and section 306.04(c) expressly forbids—prescribing controlled substances for the purpose of maintenance. The government intended to prove that respondent "was not issuing * * * prescriptions to detoxify [addicts], but retaining them as drug addicts" (App. 36–37).

In October, 1972, respondent was tried on an indictment which had been reduced to 40 counts (Tr. 4–5),[7] charging the unlawful distribution and dispensation of methadone from September 27, 1971 to February 9, 1972, to nine of the twenty-five recipients originally named in the indictment.[8] The jury convicted respondent on 22 counts. Respondent was sentenced to concurrent terms of five to fifteen years' imprisonment on fourteen counts, and to concurrent terms of ten to thirty years' imprisonment on the remaining eight counts, the latter group to run consecutively to the former. He was fined a total of $150,000, a special parole term of twelve years was imposed on each count (to run concurrently as to all counts), and his license to practice medicine in the District of Columbia was revoked pursuant to 2 D.C. Code 131 (App. 139–141).[9]

[7] References to the transcript will be to the appendix filed in this Court when the transcript excerpts have been included therein. Otherwise, transcript references will be to transcript pages only, with the exception of the transcript of October 20, 1972, which is separately paginated and will be referred to as "Tr. V."

[8] The government dismissed two of these 40 counts at the close of its case, and 38 counts were submitted to the jury for its consideration. The indictment as submitted to the jury is included in the appendix filed in this Court. See App. 30–34.

[9] 2 D.C. Code 131 provides that if a licensed or registered physician is "convicted in the District of Columbia of any felony, the court, without further hearing or procedure, may suspend * * * or may revoke, the license or registration of the defendant, in addition to imposing any other penalty pro-

2. The evidence at trial established that respondent systematically prescribed methadone in a manner inconsistent with any accepted form of medical treatment of addicts—whether by detoxification or maintenance.[10] It demonstrated that he engaged in conduct that the court of appeals described as "highly irregular practices" (Pet. App. 4a):

> 1. He prescribed methadone in whatever quantities the patient requested;
> 2. His fees were graduated in accordance with the quantity of methadone prescribed;
> 3. He did not make certain that the patients for whom he was prescribing methadone were addicts. Some were not, and some delivered their methadone to nonpatients.

Respondent's operation was of vast magnitude. Between September 1, 1971, and February 11, 1972, 11,169 prescriptions for dolophine tablets written by

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vided by law." It also provides, however, that "[a]n appeal by the defendant in any such case from the conviction of the offense shall act as a suspersedeas to the judgment of the court suspending or revoking his license or registration."

[10] Respondent's defense at trial with respect to all of the counts was that he had prescribed methadone in good faith for the purpose of detoxification (Tr. 649). He did not object to the following jury instruction (App. 123):

"Thirdly, you must also find beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." See Tr. V 67–69, 72–79, 149. In any event, federal regulations applicable to respondent at the time prohibited the prescribing of narcotic drugs for other than detoxification purposes. See note 6, *supra*.

respondent were filled at three pharmacies in the District of Columbia.[11] Of these, 5,486 prescriptions were for 50 tablets each; 1,126 were for 75 tablets; 4,225 were for 100 tablets; 214 were for 150 tablets; 9 were for 200 tablets; 5 were for 300 tablets; and 109 were for miscellaneous quantities. There were 54 days when respondent wrote more than 100 prescriptions (App. 74–77; Gov't. Exhs. 22A, 22B and 22C). In other words, in a five and one-half month period, respondent wrote prescriptions for more than 800,000 dolophine tablets.

Respondent had a "sliding-fee scale" of charging patients which was pegged solely to the quantity of pills prescribed and had no relationship whatsoever to the medical services purportedly performed. Thus, he charged $15 for a fifty-tablet prescription, $25 for seventy-five tablets, $35 for 100 tablets and $50 for 150 tablets (App. 104; Tr. 661–662). If a "patient" did not have the money to pay, respondent refused to give him a prescription (Tr. 231). At these rates, for the number of dolophine tablets prescribed, respondent took in at least $260,000 in five and one-half months.

While respondent claimed to have prescribed only to addicts for purposes of treatment, the evidence at trial showed that he made only the most superficial examinations to determine initially whether his patients were in fact addicts. This consisted typically of a request to see the addict's needle marks on his arm—which in more than one instance were simulated (Tr.

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[11] There may have been additional prescriptions filled elsewhere.

256; App. 91); a urinalysis—which was unsupervised (App. 47; Tr. 496), was easily falsified (Tr. 258) and whose results respondent regularly ignored (App. 50, 95; Tr. 344); and the question, "What can I do for you?" (App. 49; Tr. 249, 501). The patient then received either liquid methadone or dolophine tablets (a form of methadone). On return visits—for which no appointments were ever scheduled—no physical examination was performed at all (App. 50, 94), and the patient received a prescription for whatever quantity of methadone tablets he requested (App. 51, 52, 94, 96).

In these circumstances, it is not surprising that many of the persons for whom respondent wrote prescriptions were not then and, in some cases, never had been narcotic addicts in need of methadone for purposes of treatment.[12]

Respondent generally did not inquire about the daily dosages of his patients, and he gave no instructions for the use of the drugs prescribed except to refer the patient to the label on the prescription bottle which read "Take as directed for detoxification" (App. 67, 69–70; Tr. 210, 303). Predictably, many of

[12] For example, Jerome Brooks testified that when he first went to see respondent he had not taken any narcotics for almost five years (App. 68); Ivan Gower testified that he was not an addict when he went to respondent's office (App. 59); William Burgee testified that he never had been an addict but entered respondent's program in order to get dolophine tablets for a friend (Tr. 247–250); and Metropolitan Police Officer Karen Bryan (who used the name "Lynn Ryan" when she went to respondent's office in an undercover capacity pretending to be an addict) testified that she had never been a user of narcotics (App. 47).

the patients simply used the tablets to get "high" (App. 43, 58, 63); others sold them on the street (App. 43, 70–71) or gave them to a friend (Tr. 248) or relative (Tr. 304–305). One witness testified that he would consume whatever quantity was necessary for him to get high and sell the rest for $1.50 per tablet (App. 43); another sold the pills to other persons for one dollar each whenever he needed money to buy more (App. 71); and yet another pointed out that the price of methadone on the street rose to about $2 a pill when respondent's office was finally closed (App. 64).[13]

Respondent conceded that he kept inadequate records of his dispensing. His records failed, for example, to show several prescriptions issued to Herbert

[13] Typical of respondent's "patients" was Forris Ensor, who originally came to respondent because he was "strung out on dilaudid" (Tr. 162–163). During the period in question he received 26 prescriptions from respondent totalling 2,575 dolophine tablets. At first Ensor was told by respondent that he would have to detoxify himself within 21 days, but when he heard nothing further about detoxification, "[he] just kept coming" (App. 53–56; Gov't Exh. 5). He went from five to 70 dolophines a day without respondent questioning him about the increasing dosages (App. 53–54, 57; Tr. 194). When Ensor left respondent's "program" in January 1972 to enter a treatment center in Baltimore, his methadone habit was bigger than his earlier dilaudid habit (Tr. 189, 192). He testified at trial that the methadone habit "for me, right now, it is impossible to get off. * * * I could have just locked myself in a room for a week and * * * [withdrawn from dilaudid]. I wouldn't have done it but it would have been easier than methadone. Methadone takes such a long time. It is just a long, drawn-out sickness, and you just—I would rather be dead" (Tr. 193–194). Eight other "patients" testified about similar experiences. See the case histories described in the court of appeals' dissenting opinion (Pet. App. 23a–26a).

Holland, who went from 100 dolophine tablets in September to 625 in January and 300 in the first eight days of February (Tr. 758–759; Gov't Exh. 16). When asked to explain his faulty record-keeping, respondent blamed his hectic schedule (Tr. 760) or the "terrible crush of people" in his office (Tr. 747).[14] In one instance, he stated, the patient "might have caught me in the drug store across the hall. * * * I also carry a script pad on me" (Tr. 740).

Respondent testified that his "method of treatment" depended on the "mental decision" of the addict that he had had enough methadone and was ready to be "deintoxified" (Tr. 658–660). Respondent said he would aid the patient in reaching this point by "counseling" (App. 103), but he apparently attached little importance to this approach. For example, one witness, who went to respondent's office two or three times a week over a five month period, testified that his visits lasted no more than thirty to sixty seconds (App. 72), hardly time for in-depth counseling. When respondent was asked where he would have found the time to consult with or counsel his patients on January 5, 1972, when he wrote 271 prescriptions, he replied: "One would have to assume from that * * * that I talked very fast or I write very fast, and possibly both" (App. 103).

Two expert witnesses for the government, Dr. David H. Fram and Dr. Thomas E. Piemme, both registered and licensed physicians, defined the scope of

[14] Respondent testified that he had "patients" coming from as far away as Atlantic City and South Carolina (Tr. 640–642).

accepted medical practice in the treatment of narcotic addicts by either detoxification or maintenance, and discussed the procedures to be followed in such treatment (App. 78–90; Tr. 405–406). In order to avoid abuse, such as "[o]verdose death, not only to patients but to others who may inadvertently use it or to whom it may be sold" (App. 88), certain procedures were considered essential in all such programs. They included a complete physical examination at the outset, adherence to the results of tests, and initial administration of the methadone at the clinic daily under the direct scrutiny of the staff (App. 84–86)—practices respondent did not follow. Dr. Fram described the detoxification procedures of the District of Columbia Drug Abuse Treatment Center, saying that during the first sixty days all methadone was dispensed and consumed at the Center under the observation of a nurse (App. 80; Tr. 388–390). No prescriptions were ever written for methadone because "it is not considered good medical practice" (App. 80; Tr. 412–413).

Both doctors were asked hypothetical questions based on the testimony of witnesses who had received methadone prescriptions from respondent. Dr. Piemme was asked about the procedures followed by respondent in treating Herbert Holland, who had received 100 ten-milligram tablets from respondent on a single day (App. 72, 87–88). Dr. Piemme responded: "That is not acceptable practice in any program that I know of anywhere in the country [for either detoxification or maintenance]" (App. 88). He said that an

addict "[e]ven [with] the largest [heroin] habit one could conceive" would not require more than eighty to one hundred milligrams of methadone a day to "block the euphoria." Patients already addicted to very large doses of methadone "can very quickly, within a matter of a day or two, be brought down to 80 to 100 milligrams of methadone a day and maintained there" (App. 89–90).

Dr. Piemme saw nothing in respondent's procedures that would justify characterizing them as "a new, effective, good-faith technique in the treatment, detoxificational cure of an addict" (Tr. 474).[15]

Dr. Fram characterized respondent's "sliding-fee scale" based on the number of tablets prescribed as not acceptable medical practice in the District of Columbia (Tr. 396–397):

[15] When asked a hypothetical question based on the procedures employed by respondent in his treatment of Roger Wheeler, Dr. Fram stated that such procedures were not acceptable medical practice for detoxification or maintenance in the District of Columbia or in the United States. They involved serious medical dangers (App. 80–83):

"One doesn't know whether he is taking it, whether somebody else is taking it. You don't know whether a child is taking it. If you are trying to detoxify a person, you don't know whether the person is being detoxified or whether they are taking more each day. Also, you have no idea if the individual is indeed taking it at all. Maybe he is continuing on heroin and selling the methadone."

When asked a second hypothetical question based on the experience of undercover officer Karen Bryan, who received three dolophine prescriptions from respondent after her urine test had come back negative for narcotics, Dr. Fram said that this was not acceptable medical practice, that he would wonder whether the patient was an addict at all, and that he would not think of giving her methadone if she was not (App. 83).

> I would say not. Accepted medical practice is that the physician treats the patient and charges for that. If a prescription is given, that is part of the treatment. What the prescription is or how many pills are given does not determine what the price is.

Dr. Piemme agreed: "That is not only not acceptable medical practice; that is unethical medical practice" (App. 89).[16]

[16] Respondent himself was thoroughly familiar with the standards of accepted medical practice in his field at the time of the events charged. His first treatment program in 1969, which was a combination of "long term" and "short term" detoxification (Tr. 605), had ended with his arrest for violations of the Harrison Narcotic Act (26 U.S.C. (1964 ed.) 4705(a)). After he testified before a grand jury and made "firm statements" that he would not engage in certain practices in regard to the prescription of methadone, the charges against him were dismissed (App. 97–100). He subsequently received from his attorney a memorandum of a meeting between respondent and an Assistant United States Attorney (App. 116, 135–138), at which respondent had agreed to abide by specific medical procedures in any future methadone program. These procedures included obtaining the medical history of patients, conducting a reasonably thorough physical examination, abiding by the results of urine tests, recording times and amounts of dosages and either having the methadone administered in his office or prescribing only so much as would be necessary for a daily dosage. At rial, however, respondent admitted having violated most of these agreements (App. 97–100, Tr. 533, 689–704, 707–711, 742–751, 753–754, 758–760, Tr. V 4).

Respondent also identified at trial a letter he had received from the Food and Drug Administration after inspection by that agency on April 2, 1971 of a methadone maintenance program he had established in July of 1970 with FDA approval. The letter set forth four changes respondent would be required to make in order to avoid losing his authorization to conduct this program. These included monitoring his patients'

3. A divided court of appeals reversed respondent's conviction. The court (per Chief Judge Bazelon) assumed that respondent had "acted wrongfully" (Pet. App. 7a). It nevertheless held that his conviction under 21 U.S.C. 841 could not be sustained because physicians registered under the Controlled Substances Act are exempt from prosecution under that section of the Act. The court based this conclusion both on "the overall scheme of the Act" (*id.* at 8a) and its legislative history, which demonstrated—the court said—Congress' intention "to treat registered and unregistered individuals differently" (*id.* at 12a). Judge MacKinnon, dissenting, rejected the majority's analysis as unsupportable by the terms of the statute, by its legislative history, and by "plain common sense" (Pet. App. 20a).[17]

SUMMARY OF ARGUMENT

Despite the overwhelming evidence at trial that respondent, a medical doctor, operated far beyond the pale of accepted medical practice, the court of appeals

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ingestion of methadone daily during the initial weeks of treatment and insuring that patients' urine specimens were collected under supervision with the results recorded for evidence of drug dependence. At trial, respondent admitted having violated these requirements. On July 28, 1971, respondent's authorization for the maintenance program was revoked (App. 107–116).

[17] Despite its reversal of respondent's conviction, the court of appeals stayed the issuance of its mandate and denied respondent's motion for immediate release on the ground that there were no conditions of release that would reasonably assure that he will not flee. On December 23, 1974, this Court denied respondent's application for release pending disposition of the petition for a writ of certiorari.

reversed his conviction on the ground that he was prosecuted under the wrong section of the Controlled Substances Act. The court held that the authorization of a physician to dispense controlled substances for legitimate medical purposes immunizes him from prosecution under the primary felony provision of the Act, 21 U.S.C. 841(a), even when he distributes narcotic drugs for clearly illegitimate purposes, and that Congress intended to exempt trafficking doctors—merely because they were doctors—from the penalties applicable to other traffickers in narcotic drugs. In reaching this conclusion, the court of appeals misread the language, the scheme and the history of the Controlled Substances Act.

1. 21 U.S.C. 841(a) makes it unlawful for "any person" to "distribute or dispense" a controlled substance, except insofar as his conduct is "authorized" by subchapter I of the Controlled Substances Act. No other provision of the Act authorizes trafficking in drugs under the guise of practicing medicine, and there is no implication in the Act that physicians are exempt from punishment under section 841 when they go beyond the bounds of professional practice to engage in such conduct. Indeed, the only authorization for physicians to deal in drugs is section 822, which requires those who deal legitimately in controlled substances to register annually with the Attorney General. Such registration, however, provides no blanket authority to distribute controlled substances, but authorizes dispensing only "by, or pursuant to the lawful order of, a practitioner" (21 U.S.C. 802 (10))—

a term which by definition includes physicians (see 21 U.S.C. 802(20))—"in the course of professional practice or research." 21 U.S.C. 802(20). Under this limited statutory authorization, when physicians distribute or dispense other than in the course of professional practice, they exceed their authorization, cease to be practitioners under the Act, and are then covered by the prohibitions of section 841(a), like anyone else.

The court of appeals concluded that because the penalty provisions in two other sections of the Act (sections 842 and 843) specifically refer to "registrants"—a word that does not appear in section 841—registrants are subject only to those penalty provisions that specifically refer to them. Although some subsections of sections 842 and 843 refer expressly to "registrants," other subsections are like section 841 in that they refer to conduct by "any person." Thus, all three penalty provisions of the Act—sections 841, 842 and 843—apply to "any person"; they focus on the actor's conduct rather than on his status as a registrant or non-registrant. Moreover, because neither section 842 nor 843 makes it a crime for a registered practitioner to distribute drugs other than for a legitimate medical purpose, the court of appeals' conclusion that registrants are governed only by sections 842 and 843 produces the anomalous result that Congress provided no criminal sanction for a registered practitioner who distributes a controlled substance for such a purpose, although such a distribution obviously is not "authorized" by the Act.

The court of appeals also erred in concluding that

Congress intended to exclude registrants from the reach of section 841 because it already had provided adequate "administrative controls" to curtail the prescription of controlled substances other than for legitimate medical purposes. The government's authority effectively to utilize those controls, however, is substantially dependent upon the power to prosecute for felony violations under section 841.

2. In describing the conduct that is "authorized" by practitioners under the Controlled Substances Act (dispensing controlled substances "in the course of professional practice or research"), Congress used virtually the same language it had in the predecessor statute, the Harrison Narcotic Act (dispensing narcotic drugs to a patient by a physician "in the course of his professional practice only"). In a series of decisions under the Harrison Act, this Court held that a physician whose dispensation or prescription of drugs amounted to trafficking in drugs was not engaged "in the course of his professional practice only." See *Webb* v. *United States,* 249 U.S. 96; *Jin Fuey Moy* v. *United States,* 254 U.S. 189; *United States* v. *Behrman,* 258 U.S. 280. By using the same language in the Controlled Substances Act as it had in the Harrison Act, Congress obviously intended that the same construction should be applied to that language, thus making the general criminal provisions of the new Act applicable to drug trafficking by physicians.

While the legislative history of the Controlled Substances Act reflects a congressional intention to make

several significant changes from the Harrison Act in order to make the punishment more rationally fit the crime charged, there is no indication that Congress intended to lessen or substantially alter the criminal liability of physicians who acted outside the bounds of professional practice by trafficking in narcotic drugs. To the contrary, the legislative history reflects a congressional awareness that unscrupulous physicians and other practitioners are a primary source of diversion of narcotic drugs into illegitimate channels and a purpose to provide the authorities with complementary regulatory and penal provisions which together could be used to prevent such diversion.

3. In view of the foregoing arguments, it is not surprising that every circuit that has considered whether physicians are subject to prosecution and conviction under section 841(a) of the Controlled Substances Act—except for the District of Columbia Circuit in the instant case—has concluded that they are.

ARGUMENT

A PHYSICIAN, REGISTERED UNDER THE CONTROLLED SUBSTANCES ACT, IS NOT IMMUNE FROM PROSECUTION UNDER THE PRIMARY FELONY PROVISION OF THE ACT, 21 U.S.C. 841, WHEN HE DISTRIBUTES A CONTROLLED SUBSTANCE OTHER THAN FOR A LEGITIMATE MEDICAL PURPOSE

The overwhelming evidence at trial demonstrated that respondent, a medical doctor, operated far beyond the pale of accepted medical practice in prescribing methadone. It showed that he did not

dispense methadone for legitimate detoxification purposes but rather, as the dissenting judge stated (Pet. App. 27a), he "preyed upon the insatiable cravings of those unfortunate victims he purported to treat solely to get their money."

As shown in the Statement, respondent's former "patients" and the undercover police officers who visited his office testified that respondent performed only the most superficial examinations, that he prescribed methadone in whatever quantities his "patients" requested, that his fees were graduated in accordance with the quantity of methadone prescribed and bore no relationship to the nature of the medical service purportedly rendered, that he made no effort to make certain that the persons to whom he prescribed methadone were in fact addicts, and that he adopted no procedures to assure that the methadone prescribed was not given to others or sold to addicts on the street. Two expert witnesses testified that the procedures employed by respondent could in no sense be viewed as acceptable medical practice. As the dissenting judge concluded (*ibid.*): "In short, Moore was a drug pusher, a trafficker in illegal narcotics," engaged in the indiscriminate sale of prescriptions for profit with only the barest pretense of a legitimate medical purpose or standard medical procedures.

Despite the abundance of evidence that respondent was no different from a street corner drug pusher although in medical garb, the court of appeals reversed his conviction on the ground that he was prosecuted under the wrong section of the Controlled Substances Act. The court held that the authorization

of a physician to dispense controlled substances for legitimate medical purposes immunizes him from prosecution under the primary felony provision of the Act, 21 U.S.C. 841(a), even when he distributes narcotic drugs for clearly illegitimate purposes, and that Congress intended to exempt trafficking doctors—merely because they were doctors—from the penalties applicable to other traffickers in narcotic drugs.

We submit that Congress did not intend such a bizarre result and that the court of appeals has misread both the language and the history of the statute. The result of the court's interpretation of the Act is that those with the greatest access to drugs and the opportunity to divert them to illegitimate uses—those registered under the Act—are subject to less significant penalties for illicit distribution than are other persons. Congress never intended to produce such an anomalous effect when it enacted the Controlled Substances Act to take the place of the Harrison Narcotic Act which—this Court repeatedly held—doctors violated by committing the same abuses in connection with "prescribing" narcotics for "patients" that respondent committed.

A. THE LANGUAGE AND THE STATUTORY SCHEME OF THE CONTROLLED SUBSTANCES ACT SHOW THAT A PHYSICIAN MAY BE PROSECUTED UNDER THE PRIMARY FELONY PROVISION OF THE ACT, 21 U.S.C. 841(a), FOR TRAFFICKING IN NARCOTIC DRUGS

1. 21 U.S.C. 841, subsection (a), of the Controlled Substances Act provides in pertinent part:

> Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

> (1) to manufacture, distribute, or dispense * * * a controlled substance; * * *.[18]

Unless respondent's conduct was justified by the "[e]xcept as authorized" clause, it violated section 841. The words "any person" cover a physician, and respondent admittedly "distribute[d] or dispense[d] * * * a controlled substance." The question therefore is whether other provisions of subchapter I of the Act authorized respondent's trafficking in drugs under the guise of practicing medicine.

No other provision explicitly authorizes that conduct, and one normally would expect that if Congress intended to sanction it, the legislature would have specifically so stated. The court of appeals held, however, that certain sections of the Act by implication reflected a congressional intent to exempt persons in respondent's position from the general penalty provisions for illegal drug dealing in section 841. The statutory provisions interlace and are somewhat complicated, but they reflect no intention to exempt physicians from punishment under section 841 when they go beyond the bounds of professional practice to traffic in drugs.

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[18] Congress has established five "schedules" of controlled substances, based upon the drugs' varying potential for abuse, accepted medical uses, and the degrees of physical or psychological dependence to which they can lead. See 21 U.S.C. 812(a) and (b). Methadone is a Schedule II controlled substance. 21 U.S.C. 812(c) (Schedule II)(b)(11). In the case of a Schedule I or II controlled substance that is a narcotic drug, a violation of section 841(a) carries with it a maximum penalty of 15 years' imprisonment, a $25,000 fine, or both, for a first offense. A second or repeat offender is subject to as much as 30 years' imprisonment, a $50,000 fine, or both. 21 U.S.C. 841(b)(1)(A).

Section 822(a) requires "[e]very person who manufactures, distributes, or dispenses any controlled substance" to register annually with the Attorney General. Section 822(b) in turn provides that persons so registered "are authorized to possess, manufacture, distribute, or dispense such substances * * * to the extent authorized by their registration *and in conformity with other provisions of this subchapter*" (emphasis supplied).[19] See generally Baumgartner and Morrell, *Pharmaceutical Industry Regulation by the Department of Justice,* 23 Syr. L. Rev. 785, 790–791, 810–813 (1972).[20]

The "other provisions of this subchapter" that define the distribution and dispensation that section 822(b) authorizes for registrants are primarily cer-

[19] Because the controlled substances contained in Schedules I and II are those with the highest potential for abuse, registration of a distributor of controlled substances "shall not entitle a registrant to * * * distribute controlled substances in schedule I or II other than those specified in the registration." 21 U.S.C. 823(c).

[20] In *United States* v. *Rosenberg*, C.A. 9, No. 74–2197, decided March 31, 1975, slip op. 7, Judge Lumbard, speaking for the court, said of section 822:

"* * * [A]ccording to the legislative history that section was added merely to 'make it clear that persons registered under this title are authorized to deal in or handle controlled substances.' House Report at 4606. This section was not part of the original bill, so it can scarcely be called an essential part of the registration scheme. Indeed, it only says that registrants are authorized to do what the Act permits them to do. Thus, in the absence of any explicit direction from Congress, we think it inappropriate to interpret that section to work a major change in the prior enforcement pattern of drug laws which heretofore have not exempted doctors who acted outside the scope of their professional practice from the penal provisions that apply generally to all persons."

tain of the definitional sections of the Act. In the case of physicians, the definitions of "dispense", "dispenser", and "practitioner" set the bounds of the authority to dispense controlled substances. Section 802(10) defines "dispense" as follows:

> The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

Authorized dispensing, therefore, is by or pursuant to the lawful order of a "practitioner." A "practitioner" in turn is defined by section 802(20) as

> * * * a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance *in the course of professional practice* or research. [Emphasis supplied.]

Thus, the only persons authorized to "dispense" controlled substances are "practitioners" who are licensed, registered or otherwise permitted to deal in such substances, and they may deliver the substances

only pursuant to a "lawful order" and "in the course of professional practice or research." Registered physicians as such have no blanket authority to dispense controlled substances; they may do so only "in the course of professional practice." However, when they distribute or dispense other than in the course of professional practice—that is, other than for a legitimate medical purpose—they exceed that authorization and cease to be practitioners authorized to dispense under the Act. They are thus covered by the prohibitions of section 841.[21]

As the First Circuit held in *United States* v. *Badia,* 490 F. 2d 296, 298–299, the "combined effect" of the statutory definitions of "dispense" and "practitioner" is to "limit the meaning of 'dispense' to delivery of controlled substances by a physician who is acting in the course of professional practice or research" and to make delivery by a physician otherwise punishable under section 841(a)(1). The Seventh Circuit agrees:

> The term dispense is defined so as to include the prescribing of a controlled substance by a practitioner which is defined to include a registrant (physician or pharmacist) who acts within the course of professional practice. 21 U.S.C. § 802(10), (20). Since the wholesale selling of prescriptions for controlled substances is beyond the scope of professional practice, a physician (or pharmacist who participates in such a scheme) is not acting as a practitioner. Thus, if such an individual's actions are not that of a practitioner they are not authorized under the subchapter and the exception clause of section 841 does not apply. [*United States* v. *Green,* C.A. 7, No. 74–1428, *et al.,* decided February 27, 1975, slip op. 15 n. 20.]

See also *United States* v. *Rosenberg, supra,* slip op. at 3.

The restriction that authorized dispensing covers only legitimate medical or other purposes in the course of professional practice also explains why Congress provided for mandatory registration of practitioners (as distinguished from other classes of registrants) by the Attorney General "if they are authorized to dispense or conduct research under the law of the State in which they practice" (21 U.S.C. 823(f)),[22] and why it exempted from the stringent

[21] Since under the statute "dispensing" is by definition a lawful act when done by a registered practitioner, a practitioner who acts beyond the scope of his authorization is properly charged under 21 U.S.C. 841(a)(1) with "distributing" rather than with "dispensing." See *United States* v. *Badia,* 490 F. 2d 298 n. 4 (C.A. 1); *United States* v. *Black,* C.A. 9, No. 73–3003, decided March 11, 1975, slip op. 1–2; *United States* v. *Rosenberg, supra,* slip op. at 15. But see *United States* v. *Leigh,* 487 F. 2d 206 (C.A. 5). The conflict between the circuits on this point is not relevant here because respondent was indicted, tried and convicted for having "knowingly and unlawfully distributed and dispensed" controlled substances (App. 30–34).

[22] Under 21 U.S.C. 823, registration of manufacturers and distributors (*e.g.,* suppliers) is discretionary with the Attorney General; he must find in each case that registration will be consistent (in regard to the manufacture of Schedule I and II controlled substances) or not inconsistent (in regard to the manufacture or distribution of all other controlled substances) "with the public interest." 21 U.S.C. 823(a) and (b). In determining the public interest, the Attorney General must consider, *inter alia,* whether "effective controls against diversion of particular controlled substances" into other than legitimate medical scientific or industrial channels can be maintained. 21 U.S.C. 823(a)(1) and (b)(1). Registration of practitioners, on the other hand, requires no such finding. Practitioners are entitled

record-keeping requirements of the Act practitioners prescribing or administering controlled substances "in the lawful course of * * * professional practice * * *" (21 U.S.C. 827(c)).[23] See Baumgartner and Morrell, *supra,* 23 Syr. L. Rev. at 810–811.

Congress obviously believed that the standards of professional conduct under which practitioners are licensed to prescribe and administer drugs in the course of professional practice would themselves provide adequate safeguards against the diversion of controlled substances into illegitimate channels. This regulatory scheme, however, affords no basis for concluding that Congress intended to exempt from the general criminal provision of section 841 physicians who exceed the boundary of proper professional practice by dealing in drugs for profit—as respondent did.

2. The court of appeals emphasized that penalty provisions in two other sections of the Act (sections

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of right to registration "if they are authorized to dispense or conduct research under the law of the State in which they practice." 21 U.S.C. 823(f).

The Narcotic Addict Treatment Act of 1974 (NATA), Pub. L. 93–281 (May 14, 1974), 88 Stat. 124, amended section 823 by adding a new subsection (g), which requires practitioners who dispense narcotic drugs for maintenance or detoxification treatment to register separately for that purpose.

[23] 21 U.S.C. 827(c) was also amended by the Narcotic Addict Treatment Act of 1974. While practitioners are still generally exempted from the record-keeping requirements, the exemption does not apply to substances that they prescribe or administer "in the course of maintenance treatment or detoxification treatment of an individual." 88 Stat. 125 (21 U.S.C. 827(c)(1)(A)).

842 and 843) specifically refer to "registrants," but that that word does not appear in section 841; and it concluded that registrants are subject only to those penalty provisions that specifically refer to them. This conclusion rests on a misreading of the statutory scheme.

Sections 842 and 843 provide lesser penalties for less serious violations of the Act than the unauthorized distribution or dispensing that section 841 prohibits. Section 842 provides for a civil penalty of $25,000 or, if the violation was committed knowingly, for imprisonment of not more than one year, a $25,000 fine, or both, for minor violations committed during the authorized manufacture, distribution, or dispensing of controlled substances, which are misdemeanors.[24] Section 843 proscribes somewhat graver misconduct, such as the distribution of a controlled substance by a registrant without an order form or the acquisition of a controlled substance by fraud or misrepresentation, with penalties of imprisonment up to four years, a fine of up to $30,000, or both, for first offenders.[25]

Both of these sections, like section 841, apply to "any person" who violates them. Some of the substantive provisions, however, specifically prohibit acts by "registrants." By definition, therefore, these are

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[24] A repeat offender is subject to a $50,000 fine, a term of imprisonment of not more than two years, or both. 21 U.S.C. 842(c)(2)(B).

[25] A repeat offender may be fined up to $60,000, imprisoned for up to eight years, or both.

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acts that only registrants could do,[26] and it was therefore necessary for Congress to use that word in defining certain of the conduct it made criminal in those sections. It does not follow, however, that Congress' failure to refer to "registrants" in the general prohibition in section 841 against "any person" engaging in unauthorized distribution or dispensation of controlled substances indicates an intention to exempt "registrants" from that provision. See *United States* v. *Rosenberg, supra,* slip op. at 8;

[26] Such as dispensation of a controlled substance by a registrant without the written prescription of a practitioner (21 U.S.C. 842(a)(1)); distribution or dispensation by a registrant of a controlled substance not authorized by the terms of his registration (21 U.S.C. 842(a)(2)); distribution by a registrant of a controlled substance not properly labelled (21 U.S.C. 842(a)(3)); or distribution by a registrant of a Schedule I or II controlled substance except pursuant to an order form (21 U.S.C. 843(a)(1)).

Persons other than registrants, however, may commit other violations of sections 842 and 843—for example, the removal, alteration or obliteration of a label on a controlled substance (21 U.S.C. 842(a)(4)); the removal, breaking, injuring or defacing of a seal placed on a controlled substance (21 U.S.C. 842(a)(7)); the use of a registration number which is fictitious, revoked, suspended or issued to another person (21 U.S.C. 843(a)(2)); the acquisition of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge (21 U.S.C. 843(a)(3)); the manufacture, distribution or possession of any punch, die, plate, stone or other thing designed to print or reproduce the trademark or other identifying mark on any drug or container so as to render such drug a counterfeit substance (21 U.S.C. 843(a)(5)); and the use of any communication facility in committing or facilitating the commission of any felony under subchapter I or II of the Controlled Substances Act (21 U.S.C. 843(b)).

United States v. *Collier,* 478 F. 2d, 268, 271–272 (C.A. 5); *United States* v. *Green, supra,* slip op. at 9.[27]

Moreover, neither section 842 nor 843 expressly prohibits a registrant from selling drugs or prescriptions for non-medical purposes. The result, as the dissenting judge pointed out (Pet. App. 45a), is that a distributor who violates the order form requirements may be imprisoned for four years (21 U.S.C. 843), but a physician or other practitioner who prescribes drugs other than for a legitimate medical purpose may go wholly unpunished or perhaps only be imprisoned for up to two years under section 842.[28]

[27] The term "registrant" is not defined in the definitional sections of the Controlled Substances Act (see 21 U.S.C. 802) and thus is not a term of art as are "dispense" and "practitioner." It would be most surprising if Congress' failure to use the word "registrant" in section 841 manifested an implicit congressional intent to exclude this group from the reach of what purports to be a generally applicable criminal penalty provision.

[28] The dissenting judge concluded that section 842 effectively does prohibit selling prescriptions for other than a legitimate medical purpose. He reasoned as follows: Section 829(a) requires a written prescription for a Schedule II controlled substance, and section 842(a)(1) makes it unlawful to distribute or dispense a controlled substance in violation of section 829. In the view of the dessenting judge, a prescription written other than for a legitimate medical purpose would actually be "fictitious * * * and thus not a valid prescription within the meaning of the Act" (Pet. App. 36a, n. 10). We believe, however, that section 829 by itself affords an uncertain basis for the criminal prosecution of a practitioner who follows the literal requirement of the section by writing out a prescription but prescribes other than for a legitimate medical purpose. The better analysis of the relationship between sections 829, 841 and 842, we believe, is as follows: Section 829 presupposes dispensing for a legitimate medical purpose and imposes additional requirements upon prescribing, violations of which are penalized by section 842; prescriptions issued other

See also *United States* v. *Green, supra,* slip op. at 10. As the dissent also noted (Pet. App. 39a), under the court's reading of the statute registrants cannot be prosecuted at all if they sell or give drugs directly to persons for other than legitimate medical purposes rather than write prescriptions for the same drugs to be filled at pharmacies—a result Congress surely could not have intended. It is equally unlikely that Congress prohibited the acquisition of drugs by a practitioner with the intent to distribute them other than for legitimate medical purposes (as it did in section 828(e)), but at the same time provided no prohibition against the actual distribution of drugs to ultimate users—the final and critical stage in the diversion of drugs to illicit use.

The proper reading of the Controlled Substances Act, then, is that all three penalty provisions apply to "any person," as they expressly state. All three focus on conduct rather than on the actor's status as a registrant or a non-registrant. Taken together, the three penalty provisions reflect a congressional intent to impose modest penalties for violations more or less dependent upon the registration scheme, but severely to punish trafficking by anyone—registrants or non-registrants. Moreover, because neither section 842 nor 843 makes it a crime for a registered practitioner to distribute drugs not in the course of professional practice, any other reading of the Act would mean that Congress provided no criminal

than for legitimate medical purposes, on the other hand, are wholly unauthorized by the Act and their issuance punishable under section 841.

sanction for a registered practitioner who distributes a controlled substance for such a purpose, although such a distribution is not "authorized" by the Act.

3. Finally, the court of appeals concluded that Congress intended to exclude registrants from the reach of section 841 because it already had provided adequate "administrative controls" in the Controlled Substances Act, which could be used to curtail the conduct of registered physicians who prescribe controlled substances other than for legitimate medical purposes.[29] The Act, however, makes the power of the government to proceed by these administrative means against registrants substantially dependent upon the power to prosecute for criminal violations under section 841.

Section 824 provides for the suspension or revocation of registrations by the Attorney General. At the time of respondent's conduct, however,[30] it permitted such action only if a registrant had filed a false application (21 U.S.C. 824(a)(1)), had had his state license revoked or suspended (21 U.S.C. 824(a)(3)), or had been convicted of a felony under drug-related

[29] Even if the court were correct in this reading of the Act, this fact would not preclude the application of criminal sanctions. Congress has often provided a variety of sanctions, both criminal and non-criminal, to regulate conduct; and the invocation of one does not preclude the existence of the other. See, *e.g.*, *Spies* v. *United States*, 317 U.S. 492, 495.

[30] The Act has since been amended by the Narcotic Addict Treatment Act of 1974 to add additional grounds for the revocation and suspension of registrations. See 88 Stat. 125 (21 U.S.C. 824(a) and (d)).

statutes (21 U.S.C. 824(a)(2)).[31] Since, under the court of appeals' holding, a practitioner's distributing other than for a legitimate medical or other professional purpose is not prohibited by the only other felony provision of the Act applicable to registrants (section 843), the effect of that holding is to make action by the Attorney General under subsection 824 (a)(2) depend upon a prior felony conviction in a state court.

Congress surely did not intend that limitation upon the Attorney General's authority. The clear implication of section 824 is that the power of the Attorney General to revoke registrations was to be complementary to, rather than to replace, prosecution of physicians under section 841 when they prescribe controlled substances for non-medical purposes. Indeed, section 824(c) expressly provides that "[revocation proceedings] shall be independent of, and not in lieu of, criminal prosecutions * * *."[32]

[31] Since, as the dissent noted (Pet. App. 40a), 2 D.C. Code 131 also requires conviction of a felony before a physician's license to practice medicine can be revoked, revocation of respondent's registration is virtually impossible under the court of appeals' decision, unless he is first tried and convicted of a felony under local narcotics laws (which, with few exceptions, provide only misdemeanor penalties in the District of Columbia) or section 843 of the Controlled Substances Act.

[32] In the article on the Controlled Substances Act by Baumgartner and Morrell, the authors note that between June 1, 1971 and January 31, 1972, BNDD suspended five practitioner registrations, and revoked two, based upon felony convictions. Baumgartner and Morrell, *supra*, 23 Syr. L. Rev. at 811–812 n. 65. They then state that "[t]he limited grounds available to BNDD to revoke or suspend a registration represent the most critical flaw in the CSA, since BNDD is left without adequate regulatory recourse against a registrant who has been issued an annual registration

B. THE LEGISLATIVE HISTORY OF THE CONTROLLED SUBSTANCES ACT MAKES CLEAR THAT CONGRESS DID NOT INTEND TO CHANGE PRIOR LAW UNDER WHICH PHYSICIANS WHO TRAFFICKED IN DRUGS WERE SUBJECT TO PROSECUTION FOR UNLAWFUL DISTRIBUTION

1. The Comprehensive Drug Abuse Prevention and Control Act of 1970, Title II of which is the Controlled Substances Act, superseded the Harrison Narcotic Act of 1914, 38 Stat. 785. Under the Harrison Act, all persons who sold or prescribed certain narcotic drugs were required to register with the Secretary of the Treasury (26 U.S.C. (1964 ed.) 4722). They were prohibited from selling or prescribing drugs except to persons with order forms issued by the Secretary (26 U.S.C. (1964 ed.) 4705). The latter requirement was inapplicable, however, to "the dispensing or distribution of narcotic drugs to a patient by a physician * * * or other practitioner registered under section 4722, *in the course of his professional practice only* * * *." 26 U.S.C. (1964 ed.) 4705(c)(1) (emphasis supplied).[33]

and thereafter commits violations of various aspects of the CSA and/or its regulations which are not sufficient to warrant a felony conviction and do not constitute a material falsification of application filed for the previous issued registration." *Id.* at 811–812. If there are "violations * * * of the CSA * * * which are not sufficient to warrant a felony conviction * * *," there must also be violations of the CSA which are sufficient to warrant a felony conviction.

[33] The Harrison Narcotic Act had other exemptions for conduct by physicians and other practitioners. For example, it was unlawful to purchase, sell, dispense, or distribute narcotic drugs except in the original stamped package or from the original stamped package (26 U.S.C. (1964 ed.) 4704(a)); but this provision did not apply to any person having in his possession any narcotic drugs "which have been obtained from a registered dealer in pursuance of a written or oral prescription * * *

Congress used virtually the same language in the Controlled Substances Act to describe the conduct that is "authorized" by practitioners—namely, dispensing controlled substances "in the course of professional practice or research." See 21 U.S.C. 802(20). When Congress used such substantially identical language, it presumably was aware of and intended to adopt the settled judicial construction of the language of the Harrison Act. See *Shapiro* v. *United States,* 335 U.S. 1, 16; *Hecht* v. *Malley,* 265 U.S. 144, 152–153; *United States* v. *Kapsalis,* 313 F. 2d 875 (C.A. 7), certiorari

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issued for legitimate medical uses by a physician, dentist, veterinary surgeon, or other practitioner registered [under the Act] * * *." 26 U.S.C. (1964 ed.) 4704(b)(1). Nor did it apply to the dispensing or administration of narcotic drugs "to a patient by a registered physician, dentist, veterinary surgeon, or other practitioner in the course of his professional practice, and where said drugs are dispensed or administered to the patient for legitimate medical purposes * * *." 26 U.S.C. (1964 ed.) 4704(b)(2). While another section of the Harrison Act made it unlawful to sell, barter, exchange or give away narcotic drugs except pursuant to a written order form, the prohibition contained therein did not apply to the sale, dispensing or distribution of such drugs by a dealer to a consumer "under and in pursuance of a written prescription issued by a physician, dentist, veterinary surgeon, or other practitioner registered [under the Act] * * *." 26 U.S.C. (1964 ed.) 4705(c)(2).

Similarly, the Drug Abuse Control Amendments of 1965 prohibited the manufacture or sale of "any depressant or stimulant" except, *inter alia*, by "practitioners * * * while acting in the course of their professional practice." 21 U.S.C. (Supp. V, 1964 ed.) 360(a) and (b). See also 26 U.S.C. (1964 ed.) 4742(b)(1) (the Marihuana Tax Act), creating a similar exception in the case of marihuana transfers by a "practitioner * * * in the course of his professional practice only * * *."

denied, 374 U.S. 856. That construction, therefore, is a proper basis for interpreting the new Act.

In a series of decisions under the Harrison Act, this Court held that a physician whose dispensation or prescription of drugs amounted to trafficking in drugs was not engaged "in the course of his professional practice only." In *Webb* v. *United States,* 249 U.S. 96, a physician and druggist had "conspired to sell large quantities of morphine to addicts under the guise of issuing and filling orders. The so-called prescriptions were issued without consideration of individual cases and for the quantities of drugs which applicants desired * * *" (*Linder* v. *United States,* 268 U.S. 5, 20). In holding that such conduct was not within the statutory exemption for professional practice, the Court stated (249 U.S. at 99–100): "[T]o call such an order for the use of morphine a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required."

The leading case involving a physician under the Harrison Act was *Jin Fuey Moy* v. *United States,* 254 U.S. 189. The evidence there showed a course of conduct strikingly similar to that of respondent, namely (*id.* at 192–193):

> * * * [D]efendant was a practicing physician in Pittsburgh, registered under the act so as to be allowed to dispense or distribute opium and its derivatives without a written order in official form, "in the course of his professional practice only"; that he was in the habit of issuing prescriptions for morphine sulphate without such written order and not in the ordinary

course of professional practice; that he issued them to persons not his patients and not previously known to him, professed morphine users, for the mere purpose, as the jury might find, of enabling such persons to continue the use of the drug, or to sell it to others; in some cases he made a superficial physical examination, in others none at all; his prescriptions called for large quantities of morphine—8 to 16 drams at a time—to be used "as directed," while the directions left the recipient free to use the drug virtually as he pleased. His charges were not according to the usual practice of medical men, but according to the amount of the drug prescribed, being invariably one dollar per dram. * * * At and about the dates specified in the indictment—the spring of the year 1917—and for more than two years before, the number of prescriptions issued by defendant and filled at [one particular] drug store ran into the hundreds each month, all calling for morphine sulphate or morphine tablets in large quantities.

The Court held (*id.* at 194):

> Manifestly the phrases "to a patient" and "in the course of his professional practice only" are intended to confine the immunity of a registered physician, in dispensing the narcotic drugs mentioned in the act, strictly within the appropriate bounds of a physician's professional practice, and not to extend it to include a sale to a dealer or a distribution intended to cater to the appetite or satisfy the craving of one addicted to the use of the drug. A "prescription" issued for either of the latter purposes

> protects neither the physician who issues it nor the dealer who knowingly accepts and fills it.

In *United States* v. *Behrman,* 258 U.S. 280, 287, the Court noted that *Webb* and *Jin Fuey Moy* had merely recognized that Congress' purpose in providing a statutory exception for the dispensing or prescription of drugs "in the course of * * * professional practice" by registered physicians was "to confine the distribution of these drugs to the regular and lawful course of professional practice, and that not everything called a prescription is necessarily such." And, as the Court said in *Linder* v. *United States, supra,* 268 U.S. at 18: "What constitutes *bona fide* medical practice must be determined upon consideration of evidence and attending circumstances. *Mere pretense of such practice, of course, cannot legalize forbidden sales* * * * (emphasis supplied).[34]

[34] In *Linder*, the charge against the physician was that he had given an addict four tablets containing morphine and cocaine, "for the sole purpose of relieving conditions incident to addiction and keeping herself comfortable" (268 U.S. at 17). In reversing the conviction, the Court noted that the indictment did not "question the doctor's good faith nor the wisdom or propriety of his action according to medical standards" and did not "allege that he dispensed the drugs otherwise than to a patient in the course of his professional practice or for other than medical purposes. * * * [W]e cannot possibly conclude that a physician acted improperly or unwisely or for other than medical purposes solely because he has dispensed to [an addict], in the ordinary course and in good faith, four small tablets of morphine or cocaine for relief of conditions incident to addiction" (268 U.S. at 17–18).

Respondent's conduct in the present case, involving large-scale narcotics trafficking over several months, is a far cry from the single small transaction involved in *Linder.*

These decisions leave no doubt that respondent's activities would have violated the Harrison Act. The question is whether, although using substantially the same language in the Controlled Substances Act as in the Harrison Act, Congress nevertheless intended the general criminal provisions of the new Act to be inapplicable to such drug trafficking by physicians. The answer is negative.

2. Nothing in the legislative history of the Controlled Substances Act indicates or even suggests that Congress intended to make such a drastic change in the criminal liability of physicians whose dispensing and prescribing of drugs goes beyond legitimate professional practice. To the contrary, such a relaxation of criminal responsibility would be inconsistent with one of the purposes of the Act which was "to strengthen existing law enforcement authority in the field of drug abuse" (84 Stat. 1236, Preamble).

The major concern of the Congress in the Controlled Substances Act was not, as the court of appeals thought, to ~~insure uniform~~ treatment of registrants and non-registrants, but to alleviate the practice under the Harrison Act and related statutes to punish drug-related conduct, by whomever done, without sufficient regard to its relative gravity. Thus, in contrast to the Harrison Act, the Controlled Substances Act subjected less serious and more technical violations by registrants to civil fines or moderate criminal penal-

ties (H.R. Rep. No. 91–1444, 91st Cong., 2d Sess. 10 (1970)). The Act also classified drugs subject to control in five schedules according to their potential for abuse and psychological and physical effects and established "penalties which are designed to correspond to violations involving substances contained in the respective schedules" (*id.* at 6). Congress also abolished all mandatory minimum sentences (a primary criticism leveled at the Harrison Act) in favor of a more flexible penalty structure giving the sentencing judge discretion (*id.* at 11), except that persons engaged in a "continuing criminal enterprise" were subjected to mandatory sentences of up to life imprisonment. 21 U.S.C. 848.

Congress thus eliminated the prior statutory practice by which differing forms of involvement with drugs were treated identically. The punishment under the Controlled Substances Act depends instead upon such factors as the danger of the drugs involved (as determined by the schedules), the intent with which the drugs are possessed or distributed and, in some instances, the age of the person to whom they are distributed (21 U.S.C. 845). See H.R. Rep. No. 91–1444, *supra,* at 10–11.

There is no indication, however, that in making these significant changes in the scope of punishment for various types of drug offenses, Congress intended to lessen or substantially alter the criminal liability of physicians who acted outside the bounds of professional practice by trafficking in narcotic drugs for

profit.[35] To the contrary, Congress was aware that "certain classes of persons, pharmacists, physicians and researchers to name a few * * * pose a great source of diversion of dangerous substances into other than legitimate channels." 116 Cong. Rec. 1663 (1970) (remarks of Senator Hruska).[36] Such persons were therefore subjected to the regulatory controls of the

[35] As the Ninth Circuit said in *United States* v. *Rosenberg*, *supra*, slip op. at 4–5:

> There is no suggestion in the legislative history that the registration provisions were intended to be a substitute for the Act's general criminal penalties. The legislative history expressly states that the Act "provides severe criminal penalties for persons engaged in illicit . . . sale of controlled drugs primarily for the profits to be derived therefrom." Since this is what Dr. Rosenberg did, the severe criminal penalties contained in section 841 were appropriately applied to him. This conclusion is buttressed by the facts that physicians were subject to the prior federal drug laws, see, e.g., Jin Fuey Moy v. United States, 254 U.S. 189 (1920), and that one of the three purposes of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (of which the Controlled Substances Act is title II) was stated in the preamble to be "to strengthen *existing* law enforcement authority in the field of drug abuse." [Emphasis added.]

[36] The House Report noted, for example, that in a recent year almost 50 percent of the 9 billion amphetamines and barbiturates produced legitimately in this country had been diverted into illicit channels. H.R. Rep. No. 91–1444, *supra*, at 7. See also Hearings on S. 1895, S. 2590, S. 2637, Narcotics Legislation, before the Subcommittee to Investigate Juvenile Deliquency of the Senate Committee on the Judiciary, 91st Cong., 1st Sess. 318–326, 426–429, 488–491, 554–555, 643–653, 749–750 (1969); Hearings on H.R. 11701 and H.R. 13743 and related bills, Drug Abuse Control Amendments, before the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, 91st Cong., 2d Sess. 373–382 (1970).

Act, despite vigorous objections from some professional organizations.[37] That regulation, however, did not reflect a congressional purpose to exclude them from the general penalty provision in section 841.

Congress viewed the regulatory and penal provisions of the Act as complementary. Registration, record-keeping, reporting and other administrative controls would permit the authorities to maintain close surveillance over registrants, and this surveillance in turn would deter diversion of narcotics from those in the legitimate distribution chain into illicit channels. Such regulation would also disclose potential sources of diversion and enable the authorities to keep them under surveillance and take any necessary penal action against them.[38] As Senator Hruska suggested in regard to the five schedules created by the Act, they "serve a twofold purpose": first, "to determine what regulatory controls will be applicable,"

[37] Had these classes of persons been excluded from the regulatory scheme, they would necessarily have been treated like "any person" under section 841 and be subject to the greater penalties that the court of appeals found do not apply because they are "registrants." It would be surprising, indeed, if the professional groups whose representatives testified in favor of exclusion of certain practitioners from the registration requirements—for reasons such as the need to encourage innovative research, freedom to practice medicine free of administrative burdens, *etc.*—would have been advocating *greater* penalties for practitioners than for other registrants, but such is the logical extension of the court of appeals' reasoning. See note 38, *infra*.

[38] While some persons who testified before the various committees of Congress regarding drug abuse legislation believed that physicians and pharmacists should not be required to comply with such complex registration schemes and other burden-

and second, "to plug into the penalty structure * * * for determining what type of penalty will be imposed for violations of the act." 116 Cong. Rec. 1664 (1970).

Thus, while Congress intended to revamp the existing structure of penalties for drug offenses in order to take into account "the seriousness of the offense" and "individual circumstances" (H.R. Rep. No. 91–1444, *supra,* at 11), the committee reports and floor debate contain no indication that Congress intended to differentiate among different categories of "persons engaged in illicit manufacture or sale of controlled drugs primarily for the profits to be derived therefrom" (*id.* at 10), based on whether or not they were registrants. Indeed, that distinction would run directly contrary to Congress' concern with "the widespread diversion, of * * * drugs out of legitimate channels into the illicit market" (*id.* at 6), and its awareness that a principal source of that diversion was unscrupulous practitioners.[39] As the Seventh Circuit has stated:

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some administrative requirements as those proposed, none expressed doubt that such persons should be—and were in fact—subject to felony prosecution in appropriate circumstances. For example, Dr. William S. Apple, Executive Director of the American Pharmaceutical Association, stated that his group "favors and will support vigorous prosecution of anyone, including pharmacists, responsible for criminal diversion of drugs from legitimate to illicit uses." Hearings on H.R. 11701 and H.R. 13743, Drug Abuse Control Amendments, *supra*, note 36, at 363. See also *id.* at 373–375, 378.

[39] That unscrupulous practitioners were a primary source of the diversion of controlled substances—particularly methadone—into the illicit market in the District of Columbia is also the subject of a recent article. See Greene, Brown and DuPont, *Controlling the Abuse of Illicit Methadone in Washington, D.C.*, 32 Arch. Gen. Psychiatry 221 (1975). The article reported that addicts entering the District of Columbia's Narcotics Treatment Administration methadone program were asked to complete questionnaires that inquired, *inter alia*, about the origin of the methadone they had purchased in the streets. In the first quarter of 1972—while respondent was still in business—32 percent of those interviewed reported that their illicit methadone was originally obtained from a private physician. By the fourth quarter of 1973, however, the figure had declined to 4 percent. *Id.* at 224. The authors attributed this decline, *inter alia*, to "eliminating the use of methadone by physicians in the private sector who were not providing the close supervision and the many ancillary services required for effective addiction treatment * * *. *The conviction and imprisonment of the worst offender among these physicians was a major deterrent to his associates' methadone prescribing.* This channel of diversion was finally sealed when the local medical and pharmaceutical professional societies voluntarily agreed to discontinue the use of methadone, making the treatment program [of the Narcotics Treatment Administration] the only legitmate source of the drug." *Id.* at 225 (emphasis supplied).

> The language in the legislative history relied on by the *Moore* court to conclude that physicians were not to be included within the coverage of section 841 is in our view too general to justify that conclusion. The congressional purpose behind section 841 was to get the drug dealer no matter who he might be, and to prevent diversion of legitimately produced controlled substances into illicit channels. One of the major sources of this illicit diversion is from registrants who have relatively easy access to controlled substances. Certainly Congress did not intend to immunize such individuals from prosecution under section 841. *United States* v. *Green, supra,* slip op. at 13; footnote omitted.]

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As we have shown, the language, the statutory scheme and the legislative history of the Controlled Substances Act make clear that physicians who traffic in narcotic drugs are subject to prosecution and conviction for unlawful distribution under section 841 (a) of the Act. It is therefore not surprising that every circuit that has considered this question, other than the District of Columbia Circuit in the instant case, has concluded that physicians are not immune from prosecution under that section. See *United States* v. *Badia,* 490 F. 2d 296 (C.A. 1); *United States* v. *Collier,* 478 F. 2d 268 (C.A. 5); *United States* v. *Leigh,* 487 F. 2d 206 (C.A. 5); *United States* v. *Green,* C.A. 7, No. 74–1428, *et al.,* decided February 27, 1975; *United States* v. *Rosenberg,* C.A. 9, No. 74–2197, decided March 31, 1975; *United States* v. *Bartee,* 479 F. 2d 484 (C.A. 10); *United States* v. *Jobe,* 487 F. 2d 268 (C.A. 10); cf. *United States* v. *Larson,* 507 F. 2d 385 (C.A. 9). Two of those decisions (*Green* and *Rosenberg*) explicitly rejected the District of Columbia Circuit's analysis of the Controlled Substances Act in the instant case. For, as the Seventh Circuit succinctly put it:

> * * * When * * * a physician acts without any legitimate medical purpose and beyond the course of professional practice by selling prescriptions that allow the bearer to obtain controlled substances his conduct should be treated like that of any street-corner pill-pusher. [*United States* v. *Green, supra,* slip op. at 9].

CONCLUSION

It is therefore respectfully submitted that the judgment of the court of appeals should be reversed.

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MAY 1975.

APPENDIX

Selected Provisions of the Controlled Substances Act, Pub. L. 91–513, 84 Stat. 1242, *et seq.* (21 U.S.C. 801 to 904)

SEC. 802. DEFINITIONS.—As used in this subchapter:

* * * * *

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance. The term "distributor" means a person who so delivers a controlled substance.

* * * * *

(20) The term "practitioner" means a physician dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

* * * * *

(27) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs. [Added May 14, 1974, Public Law 93–281, § 2, 88 Stat. 124.]

(28) The term "detoxification treatment" means the dispensing, for a period not in excess of twenty-one days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period. [Added May 14, 1974, Public Law 93–281, § 2, 88 Stat. 124.]

* * * * *

SEC. 812. SCHEDULES OF CONTROLLED SUBSTANCES—ESTABLISHMENT.

* * * * *

(a) There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules

established by this section shall be updated and republished on a semi-annual basis during the two-year period beginning one year after the date of enactment of this subchapter and shall be updated and republished on an annual basis thereafter.

(b) Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on the effective date of this part, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

* * * * *

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe phychological or physical dependence.

* * * * *

(c) Initial schedules of controlled substances.

Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

* * * * *

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.
(2) Anileridine.
(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.

(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.
(12) Methadone - Intermediate, 4 - cyano - 2 - dimethylamino-4,4-diphenyl butane.
(13) Moramide - Intermediate, 2 - methyl - 3 - morpholino-1,1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4 - cyano - 1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.
(20) Racemethorphan.
(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

* * * * *

SEC. 821. RULES AND REGULATIONS.—The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.

SEC. 822. PERSONS REQUIRED TO REGISTER.—

(a) Annual registration.—Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain annually a registration issued by the At-

torney General in accordance with the rules and regulations promulgated by him.

(b) Authorized activities.—Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions.—The following persons shall not be required to register and may lawfully possess any controlled substance under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 802 (25) of this title.

(d) Waiver.—The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration.—A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) Inspection.—The Attorney General is authorized to inspect the establishment of a registrant or

applicant for registration in accordance with the rules and regulations promulgated by him.

SEC. 823. REGISTRATION REQUIREMENTS—MANUFACTURERS OF CONTROLLED SUBSTANCES IN SCHEDULES I AND II.

(a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
(2) compliance with applicable State and local law;
(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
(4) past experience in the distribution of controlled substances; and
(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;
(2) compliance with applicable State and local law;
(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and
(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
(2) compliance with applicable State and local law;
(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Practitioners shall be registered to dispense or conduct research with controlled substances in schedule II, III, IV, or V if they are authorized to dispense or conduct research under the law of the State in which they practice. Separate registration under this part for practitioners engaging in research with nonnarcotic controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Pharmacies (as distinguished from pharmacists) when engaged in commercial activities, shall be registered to dispense controlled substances in schedule II, III, IV, or V if they are authorized to dispense under the law of the State in which they regularly conduct business. Registration application by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of the each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title.

(g) Practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(1) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(3) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment. [Added May 14, 1974, Pub. L. 93–281, § 3, 88 Stat. 124.]

SEC. 824. DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATIONS.—

(a) Grounds.—A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any

State, relating to any substance defined in this subchapter as a controlled substance; or

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances.

A registration pursuant to section 823(g) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g) of this title. [As amended, May 14, 1974, Pub. L. 93–281, § 4, 88 Stat. 125.]

(b) Limits of revocation or suspension.—The Attorney General may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings.—Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of Title 5. Such proceedings shall be independent of, and not in lieu of,

criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(d) Suspension of registration in cases of imminent danger.—The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction. [As amended, May 14, 1974, Pub. L. 93–281, § 4, 88 Stat. 125.]

* * * * *

SEC. 827. RECORDS AND REPORTS OF REGISTRANTS—INVENTORY.

(a) Except as provided in subsection (c) of this section—

(1) every registrant under this subchapter shall, on the effective date of this section, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more

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than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after the effective date of this section, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) The foregoing provisions of this section shall not apply—

(1)(A) with respect to any narcotic controlled substance in schedule II, III, IV, or V, to the prescribing or administering of such substance by a practitioner in the lawful course of his professional practice unless such substance was prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual [as amended, May 14, 1974, Pub. L. 93–281, § 5, 88 Stat. 125]; or

(B) with respect to nonnarcotic controlled substances in schedule II, III, IV, or V, to any practitioner who dispenses such substances to his patients, unless the practitioner is regularly engaged in charging his patients, either separately or together with charges for other professional services, for substances so dispensed [as amended, May 14, 1974, Pub. L. 93–281, § 5, 88 Stat. 125];

(2) (A) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 355(i) or 360b(j) of this title;

(B) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this subchapter.

(d) Every manufacturer registered under section 823 of this title shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery, or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances,

identifying by the registration number assigned under this subchapter the person or establishment (unless exempt from registration under section 822(d) of this title) to whom such sale, delivery, or other disposal was made.

* * * * *

SEC. 828. ORDER FORMS.

(a) Unlawful distribution of controlled substances.—It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section and regulations prescribed by him pursuant to this section.

* * * * *

(d) Issuance.

(1) The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) of this section only to persons validly registered under section 823 of this title (or exempted from registration under section 822(d) of this title). Whenever any such form is issued to a person, the Attorney General shall, before delivery thereof, insert therein the name of such person, and it shall be unlawful for any other person (A) to use such form for the purpose of obtaining controlled substances or (B) to furnish such form to any person with intent thereby to procure the distribution of such substances.

(2) The Attorney General may charge reasonable fees for the issuance of such forms in such amounts as he may prescribe for the purpose of covering the cost to the United States of issuing such forms, and other necessary activities in connection therewith.

(e) Unlawful acts.—It shall be unlawful for any person to obtain by means of order forms issued under this section controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research.

SEC. 829. PRESCRIPTIONS.

(a) Schedule II substances.—Except when dispensed directly by a practitioner other than a pharmacist, to an ultimate user, no controlled substance in scedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 353(b) of this title. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

* * * * *

SEC. 841. PROHIBITED ACTS A.

(a) Unlawful acts.—Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

(b) Penalties.—Except as otherwise provided in section 845 of this title, any person who violates subsection (a) of this section shall be sentenced as follows:

(1)(A) In the case of a controlled substance in schedule I or II which is a narcotic drug, such person shall be sentenced to a term of imprisonment of not more than 15 years, a fine of not more than $25,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 30 years, a fine of not more than $50,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 6 years in addition to such term of imprisonment.

(B) In the case of a controlled substance in schedule I or II which is not a narcotic drug or in the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 5 years, a fine of not more than $15,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimu-

lant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine of not more than $30,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 4 years in addition to such term of imprisonment.

* * * * *

(4) Notwithstanding paragraph (1)(B) of this subsection, any person who violates subsection (a) of this section by distributing a small amount of marihuana for no remuneration shall be treated as provided in subsections (a) and (b) of section 844 of this title.

* * * * *

SEC. 842. PROHIBITED ACTS B.

(a) Unlawful acts.—It shall be unlawful for any person—

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title;

(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title;

(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration,

order or order form, statement, invoice, or information, required under this subchapter or subchapter II of this chapter;

(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824(f) or 881 of this title or to remove or dispose of substances so placed under seal; or

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled to protection.

(b) Manufacture.—It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II which is—

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 826 of this title; or

(2) in excess of a quota assigned him pursuant to section 826 of this title.

(c) Penalties.

(1) Except as provided in paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution

and laws of the United States) shall have jurisdiction in accordance with section 1355 of Title 28 to enforce this paragraph.

(2)(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine of not more than $25,000, or both.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of $50,000, or both.

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

Sec. 843. Prohibited Acts C.

(a) Unlawful Acts.—It shall be unlawful for any person knowingly or intentionally—

(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 828 of this title;

(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter; or

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance.

(b) Communication facility.—It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this subchapter or subchapter II of this chapter. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term "communication facility" means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communications.

(c) Penalties.—Any person who violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine of not more than $30,000, or both; except that if any person commits

such a violation after one or more prior convictions of him for violation of this section, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 8 years, a fine of not more than $60,000, or both.

* * * * *

SEC. 845. DISTRIBUTION TO PERSONS UNDER AGE TWENTY-ONE.

(a) Any person at least eighteen years of age who violates section 841(a)(1) of this title by distributing a controlled substance to a person under twenty-one years of age is (except as provided in subsection (b) of this section) punishable by (1) a term of imprisonment, or a fine, or both, up to twice that authorized by section 841(b) of this title, and (2) at least twice any special parole term authorized by section 841(b) of this title, for a first offense involving the same controlled substance and schedule.

(b) Any person at least eighteen years of age who violates section 841(a)(1) of this title by distributing a controlled substance to a person under twenty-one years of age after a prior conviction or convictions under subsection (a) of this section (or under section 333(b) of this title as in effect prior to the first day of the seventh calendar month that begins after October 26, 1970) have become final, is punishable by (1) a term of imprisonment, or a fine, or both, up to three times that authorized by section 841(b) of this title,

and (2) at least three times any special parole term authorized by section 841(b) of this title, for a second or subsequent offense involving the same controlled substance and schedule.

* * * * *

SEC. 848. CONTINUING CRIMINAL ENTERPRISE—PENALTIES; FORFEITURES.

(a) (1) Any person who engages in a continuing criminal enterprise shall be sentenced to a term of imprisonment which may not be less than 10 years and which may be up to life imprisonment, to a fine of not more than $100,000, and to the forfeiture prescribed in paragraph (2); except that if any person engages in such activity after one or more prior convictions of him under this section have become final, he shall be sentenced to a term of imprisonment which may not be less than 20 years and which may be up to life imprisonment, to a fine of not more than $200,000, and to the forfeiture prescribed in paragraph (2).

(2) Any person who is convicted under paragraph (1) of engaging in a continuing criminal enterprise shall forfeit to the United States—

(A) the profits obtained by him in such enterprise, and

(B) any of his interest in, claim against, or property or contractual rights of any kind affording a source of influence over, such enterprise.

(b) For purposes of subsection (a) of this section, a person is engaged in a continuing criminal enterprise if—

(1) he violates any provision of this subchapter or subchapter II of this chapter the punishment for which is a felony, and

(2) such violation is a part of a continuing series of violations of this subchapter or subchapter II of this chapter—

(A) which are undertaken by such person in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management, and

(B) from which such person obtains substantial income or resources.

(c) In the case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended, probation shall not be granted, and section 4202 of Title 18 and the Act of July 15, 1932 (D.C. Code, secs. 24–203 to 24–207), shall not apply.

(d) The district courts of the United States (including courts in the territories or possessions of the United States having jurisdiction under subsection (a) of this section) shall have jurisdiction to enter such restraining orders or prohibitions, or to take such other actions, including the acceptance of satisfactory performance bonds, in connection with any property or other interest subject to forfeiture under this section, as they shall deem proper.

* * * * *

Regulation

21 C.F.R. 306.04 PURPOSE OF ISSUE OF PRESCRIPTION

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting

to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

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26 U.S.C. (1964 ed.) 4701, *et seq.* (The Harrison Narcotic Act of 1914)

* * * * *

SEC. 4704. Packages.

(a) General requirement.—It shall be unlawful for any person to purchase, sell, dispense, or distribute narcotic drugs except in the original stamped package or from the original stamped package; and the absence of appropriate taxpaid stamps from narcotic drugs shall be prime facie evidence of a violation of this subsection by the person in whose possession the same may be found.

(b) Exceptions in case of registered practitioners.—

The provisions of subsection (a) shall not apply—

(1) Prescriptions.

To any person having in his or her possession any narcotic drugs or compounds of narcotic drug which have been obtained from a registered dealer in pursuance of a written or oral prescription referred to in section 4705 (c) (2), issued for legitimate medical uses by a physician, dentist, veterinary surgeon, or other practitioner registered under section 4722; and where the bottle or other container in which such narcotic drug or compound of a narcotic drug may be put up by the dealer upon said prescription bears the name and registry number of the druggist, and name and address of the patient, serial number of prescription, and name, address, and registry number of the person issuing said prescription; or

(2) Dispensations direct to patients.

To the dispensing, or administration, or giving away of narcotic drugs to a patient by a registered physician, dentist, veterinary surgeon, or other practitioner in the course of his professional practice, and where said drugs are dispensed or administered to the patient for legitimate medical purposes, and the record kept as required by this subpart of the drugs so dispensed, administered, distributed, or given away.

SEC. 4705. Order forms.

(a) General requirement.—It shall be unlawful for any person to sell, barter, exchange, or give away narcotic drugs except in pursuance of a written order of the person to whom such article is sold, bartered, exchanged, or given, on a form to be issued in blank for that purpose by the Secretary or his delegate.

* * * * *

(c) Other exceptions.—Nothing contained in this section, section 4735, or section 4774 shall apply—

(1) Use of drugs in professional practice. To the dispensing or distribution of narcotic drugs to a patient by a physician, dentist, veterinary surgeon, or other practitioner registered under section 4722, in the course of his professional practice only * * *

* * * * *

SEC. 4722. Registration.

On or before July 1 of each year every person who engages in any of the activities enumerated in section 4721 shall register with the Secretary or his delegate his name or style, place of business and place or places where such business is to be carried on, and every person upon first engaging in any such activities shall immediately make like registration.

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